

SECTION 11

MAR 25 2013

510(k) Summary Prepared March 6, 2013

Sponsor: Siemens Medical Solutions USA, Inc.,
Ultrasound Division
685 East Middlefield Road
Mountain View, California 94043

Contact Person: Patrick Lynch
Telephone: (650) 694-5658

Submission Date: March 6, 2013

Modified Device Name: ACUSON SC2000 Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound System

Classification:

Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX
Diagnostic Intravascular Catheter	FR # 870.1200	Product Code OBJ

A. Legally Marketed Predicate Devices

The modified Diagnostic Ultrasound System is substantially equivalent to the company's previously cleared device (K123622).

B. Device Description:

The Acuson SC2000™ has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- Safety and EMC Requirements for Medical Equipment
- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

C. Intended Use

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Intraoperative Abdominal, Intraoperative, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or jugular veins in the neck; superficial and deep veins and arteries in the arms and legs; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during intraoperative procedures.

Transcranial Imaging Applications

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology.

The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

D. Substantial Equivalence

The submission device is substantially equivalent to the predicate with regard to both intended use and technological characteristics. This modification is intended only to rename three transducers, as described in the table below.

Predicate Device (K123622)	Submission Device
Current Name	Modified Name
8V3c	8V3
V5M TEE	V5Ms
AUX CW2	CW2

E. Performance Data

No performance data required to support this modification, as there is no change to any hardware or software, or method of use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 25, 2013

Siemens Medical Solutions, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K130754
Trade/Device Name: SC2000™ Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, OBJ
Dated: March 18, 2013
Received: March 19, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson SC2000™ Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

9L4
V5Ms
4V1c
8V3
CW2
4Z1c

AcuNav 8F and 10F Ultrasound Catheter
ACUSON AcuNav™ V 10F Ultrasound
Catheter
SoundStar 10F Ultrasound Catheter
V7M TEE
10V4

Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130754

Device Name: SC2000™ Diagnostic Ultrasound System

Indications For Use:

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Abdominal Intraoperative, Intraoperative Neurological, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The typical examinations performed using the SC2000 Ultrasound System are:

Cardiac Imaging Applications and Analysis

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

The system transmits ultrasound energy from either a transthoracic or transesophageal approach in adult and pediatric patients; and from a transthoracic approach in neonatal and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Vascular Imaging Applications and Analysis

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or jugular veins in the neck; superficial and deep veins and arteries in the arms and legs; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Superficial Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

Intraoperative Imaging Applications

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during neurological intraoperative procedures.

Transcranial Imaging Applications

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology.

The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **SC2000 Diagnostic Ultrasound System**

Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D	Other: Real Time 3D
Ophthalmic												
Fetal		P	P	P	P	P	P		P*	P		P
Abdominal		P	P	P	P	P	P		P*	P		
Intraoperative Abdominal		P	P	P	P	P	P		P*	P		
Intraoperative Neurological		P	P	P		P	P	P	P*	P		
Pediatric		P	P	P	P	P	P		P*	P	P	P
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic		P	P	P	P	P	P		P*	P		
Cardiac		P	P	P	P	P	P		P*	P	P	P
Trans-esophageal		P	P	P	P	P			P*		P	
Transrectal												
Transvaginal												
Transurethral												
Intra-Luminal		P	P	P	P	P	P		P*			P
Peripheral Vessel		P	P	P	P	P	P	P	P*	P		
Laparoscopic												
Musculo-skeletal Conventional		P	P	P		P	P	P	P*	P		
Musculo-skeletal Superficial		P	P	P		P	P	P	P*	P		
Other (Neonatal Cardiac)		P	P	P	P	P	P		P*	P		
Other (Intra-Cardiac)		P		P	P	P	P		P*			P

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K113179, K123622

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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 Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)
 Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **9L4**

Indications for Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological		P	P	P		P	P	P	P*	P
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel		P	P	P		P	P	P	P*	P
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P	P	P*	P
Musculo-skeletal Superficial		P	P	P		P	P	P	P*	P
Other (specify)										

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K113179, K123622

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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 Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)
 Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VSM TEE**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*		P
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*		P
Trans-esophageal		P	P	P	P	P			P*		P
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K113179, K123622

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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 Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)
 Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4V1c**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P *	P
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P *	P
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		P *	P
Cardiac		P	P	P	P	P	P		P *	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Neonatal Cardiac)		P	P	P	P	P	P		P *	P

N=new indication. Previously Cleared in 510(k) K072365, K102017, K113179, K123622

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)
Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **8V3c**

Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P *	P
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P *	P
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P *	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Neonatal Cardiac)		P	P	P	P	P	P		P *	P

N=new indication. Previously Cleared in 510(k) K102017, K113179, K123622

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **AUX CW2**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric					P					
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication. Previously Cleared in 510(k) K072365, K102017, K113179, K123622

Additional Comments:

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Concurrence of CDRH, Office of In-Vitro Diagnostics (OIVD)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4Z1c**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal		P	P	P	P	P			P*	P	P
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*	P	P
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K113179, K123622

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **AcuNav 8F and 10F Ultrasound Catheter**

Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*		
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	P	P	P	P	P		P*		
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra-Cardiac)		P	P	P	P	P	P		P*		

N=new indication, P = Previously Cleared in 510(k) K071234, K093812, K113179, K123622

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **ACUSON AcuNav™ V 10F Ultrasound Catheter**

Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*		P
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	P	P	P	P	P		P*		P
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra-Cardiac)		P	P	P	P	P	P		P*		P

N=new indication. P = Previously Cleared in 510(k) K081808, K113179, K123622

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **SoundStar 10F Ultrasound Catheter**

Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	P	P	P	P	P		P*		
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra-Cardiac)		P	P	P	P	P	P		P*		

N=new indication. P = Previously Cleared in 510(k) K070242, K113179, K123622

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V7M TEE**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophthalmic											
Fetal											
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*		P
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*		P
Trans-esophageal		P	P	P	P	P			P*		P
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K111674, K123622

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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 Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)
 Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **10V4**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P *	P
Abdominal		P	P	P	P	P	P		P *	P
Intraoperative Abdominal		P	P	P	P	P	P		P *	P
Intraoperative Neurological		P	P	P	P	P	P		P *	P
Pediatric		P	P	P	P	P	P		P *	P
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P *	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Neonatal Cardiac)		P	P	P	P	P	P		P *	P

N=new indication. Previously Cleared in 510(k) K111674, K123622

Additional Comments:

*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) _K130754_

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